

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 19 MAY 2006

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Applicant's or agent's file reference 700953-53661	FOR FURTHER ACTION		See Form PCT/IPEA/416																								
International application No. PCT/US04/37810	International filing date (day/month/year) 12 November 2004 (12.11.2004)	Priority date (day/month/year) 12 November 2003 (12.11.2003)																									
International Patent Classification (IPC) or national classification and IPC IPC: A61K 48/00(2006.01);C12N 15/00(2006.01),15/63(2006.01),15/74(2006.01),5/00(2006.01) USPC: 514/44;435/320.1,325,455																											
Applicant THERION BIOLOGICS CORPORATION																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ____ sheets, as follows:</p> <div style="margin-left: 40px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																											
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 07 April 2005 (07.04.2005)		Date of completion of this report 24 April 2006 (24.04.2006)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Anne Marie S. Wehbe <i>J. Roberts for</i> Telephone No. (571) 272-1600																									

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/37810

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☐ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
 pages 1-81 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the claims:
 pages 82 and 83 as originally filed/furnished
 pages* NONE as amended (together with any statement) under Article 19
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the drawings:
 pages 1-15 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages None
- ☒ the claims, Nos. None
- ☒ the drawings, sheets/figs None
- ☒ the sequence listing (*specify*): None
- ☒ any table(s) related to the sequence listing (*specify*): None

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/37810

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 2 in part, 3, 6-22

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 2 in part, 3, 6-22 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 2 is a multiple dependent claims that depends in the alternative on itself. Claim 2 has only been considered to the extent that it depends on claim 1. Claims 3, and 6-22 are improper multiple dependent claims under PCT Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☐ no international search report has been established for said claims Nos. _____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/37810**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>23-24</u>	YES
	Claims <u>1-2, 4-5</u>	NO
Inventive Step (IS)	Claims <u>24</u>	YES
	Claims <u>1-2, 4-5, 23</u>	NO
Industrial Applicability (IA)	Claims <u>1-2, 4-5, 23-24</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-2, 4, and 5 lack novelty under PCT Article 33(2) as being anticipated by AARTS W. M. et al. Canc. Res. October 15 2002, Vol. 62, 5770-5777. Aarts et al. teaches an avipox vector which encodes CEA and three co-stimulatory molecules, B7-1, ICAM-1 and LFA-3 (Aarts et al., page 5770, abstract and page 5771). Aarts et al. further teaches the generation of anti-CEA immune responses and antitumor activity following administration of the vector (Aarts et al., page 5775-5776). Thus, by teaching all the limitations of the claims as written, Aarts anticipates the instant claims.

Claims 1-2 and 4 lack novelty under PCT Article 33(2) as being anticipated by SCHOLL et al. J. Biomed. Biotech. August 2003, Vol. 3, 194-201. Scholl et al. teaches the generation of antitumor immune responses following the administration of a single vaccinia virus encoding MUC-1 and IL-2 to breast cancer patients (Scholl et al., page 195, and 200). Thus, by teaching all the limitations of the claims as written, Scholl et al. anticipates the instant claims.

Claim 23 lacks an inventive step under PCT Article 33(3) as being obvious over SCHLOM et al. Breast Canc. Res. Treat. 1996, Vol. 38, 27-39 in view of ZAJAC et al. Human Gene Ther. November 1 2003, Vol. 14, 1497-1510. Schlom et al. teaches two different vaccinia viruses encoding the breast cancer antigens MUC-1 and CEA, and the individual use of the vectors to generate anti-tumor responses (Schlom et al., pages 28-29). Zajac et al. supplements Schlom by teaching a single vaccinia vector encoding 3 different tumor antigens (Zajac et al., page 1501, Figure 2). Zajac et al. provides motivation for expressing more than one tumor antigen in the same vector in order to circumvent antigen expression heterogeneity in tumor and immune escape (Zajac et al., page 1498, column 1). Therefore, based on the motivation to express more than one tumor antigen in the same vector, it would have been obvious to modify the vectors taught by Schlom et al. to encode both CEA and MUC-1.

Claim 24 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a single poxvirus vector encoding CEA and a wobbled MUC-1.

Claims 1-2, 4-5, and 23-24 meet the criteria set out in PCT Article 33(4) for industrial applicability as the kits and methods can be used in breast cancer therapy.